

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**SYMED LABS LIMITED, *et al.*,**

**Plaintiffs,**

**v.**

**ROXANE LABORATORIES, INC.,**

**Defendant.**

**Civil Action No. 15-8304 (CCC)  
(LEAD DOCKET)**

**SYMED LABS LIMITED, *et al.*,**

**Plaintiffs,**

**v.**

**GLENMARK PHARMACEUTICALS  
INC., USA,**

**Defendant.**

**Civil Action No. 15-8306 (CCC)  
(CONSOLIDATED)**

**SYMED LABS LIMITED, *et al.*,**

**Plaintiffs,**

**v.**

**AMNEAL PHARMACEUTICALS, LLC,**

**Defendant.**

**Civil Action No. 15-8307 (CCC)  
(CONSOLIDATED)**

**OPINION**

**FALK, U.S.M.J.**

The above matters are consolidated patent infringement actions. Plaintiffs, Symed Labs and Hetero USA, are the owners by assignment of four patents covering a linezolid-based product, Zyvox®, which is a strong antibiotic. Defendants Roxane Labs, Glenmark Pharmaceuticals, and Amneal Pharmaceuticals produce, or seek to produce, generic versions of Plaintiffs' Zyvox product.

Before the Court is Plaintiffs' omnibus motion to amend **(1)** the Complaints in each of the three cases to assert claims of willful infringement and infringement pursuant to the doctrine of equivalents, and to withdraw certain claims; **(2)** their infringement contentions; and **(3)** their responses to Defendants' invalidity contentions. [Civ. A. No. 15-8304; ECF No. 202.] Oral argument was held on October 25, 2018. For the reasons set forth below, Plaintiffs' motion to amend the Complaints is **GRANTED IN PART AND DENIED IN PART**; Plaintiffs' motion to amend infringement contentions is **DENIED**; and Plaintiffs' motion to amend their responses to invalidity contentions is **GRANTED**.

**I. Relevant Background**

In November 2015, Plaintiffs filed three patent infringement actions alleging that Defendants infringed U.S. Patent Nos. 7,714,128 ("the '128 patent"); 7,718,799 ("the '799 patent"); 7,718,800 ("the '800 patent"); and 7,732,597 ("the '597 patent"). Plaintiffs acknowledge that their pleadings were prepared in accordance with Form 18, which was then part of Federal Rule of Civil Procedure 84 and, if

properly employed, deemed sufficient to allege direct patent infringement. (Pls.’ Br. 3.)<sup>1</sup> Plaintiffs also acknowledge that the Complaints do not explicitly allege willfulness as part of the case. (Id.)

In February 2018, with discovery about to be closed, the Court held a conference to address last-minute discovery disputes. Chief among them was Plaintiffs’ request to compel responses to discovery they had served on the question of, among other things, willful infringement. Defendants objected to producing responses to any such discovery because it was not relevant because willful infringement was not pleaded and was not part of the case. Plaintiffs requested, and were granted, permission to file the current motion to amend, seeking to bring the issue into the case and expand discovery and infringement contentions to include it.

## **II. Request to Amend Complaints**

The specific amendments sought are to: **(1)** plead new claims alleging willful infringement in all three cases; **(2)** “to reserve the right to assert the doctrine of equivalents after the Court’s claim construction”; **(3)** withdraw claims for infringement of Plaintiffs’ “process patents” (all patents except for the ‘128 patent); and **(4)** add two parties to the Complaint (Roxane West-Ward Pharmaceuticals International Limited and West-Ward Pharmaceuticals Corp., the current holder of Roxane’s ANDA and its U.S. agent, respectively).

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<sup>1</sup> Rule 84 was abrogated as part of amendments to the Federal Rules of Civil Procedure effective December 1, 2015. *See, e.g., Robern v. Glasscrafters, Inc.*, 206 F. Supp. 3d 1005, 1008 (D.N.J. 2016).

Defendants do not oppose requests (3) and (4). Defendants strongly oppose requests (1) and (2).

The deadline to amend pleadings was September 8, 2016. (*See* Sixth Amended Scheduling Order ¶ 14 (ECF No. 104).) Because the scheduling order deadline in this case has passed, Federal Rule of Civil Procedure 16(b)'s "good cause" standard applies to the request to amend. Only if good cause is shown does the analysis move to the more lenient Rule 15 inquiry. *See, e.g., Eastern Minerals & Chem. Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000); *Stallings ex rel. Estate of Stallings v. IBM Corp.*, 2009 WL 2905471, at \*16 (D.N.J. Sept. 8, 2009).

**A. Legal Standards**

**(I) Rule 16**

Rule 16(b)(4) provides in relevant part: "A schedule may be modified only for good cause." A request to file an amended pleading after a deadline contained in a scheduling order implicates Rule 16(b). *See Dimensional Commc'n Inc. v. Oz Optics, Ltd.*, 148 Fed. Appx. 82, 85 (3d Cir. 2006). Good cause largely depends on the diligence of the moving party. *Harrison Beverage Co. v. Dribeck Importers, Inc.*, 133 F.R.D. 463, 469 (D.N.J. 1990). To establish good cause, the movant must show that "despite its diligence, it could not reasonably have met the scheduling order deadline." *Hutchins v. United Parcel Service*, No. 01-1462, 2005 WL 1793695, at \*3 (D.N.J. July 26, 2005). What will constitute "good cause" to warrant modification "necessarily varies with the circumstances of each case." 6A Alan Wright et al.,

*Federal Practice & Procedure* § 1522.2, at 313 (3d ed. 2010). The Court therefore has “great discretion in determining what kind of showing the moving party must make in order to satisfy the good cause requirement of Rule 16(b).” *Thoman v. Philips Med. Sys.*, No. 04-3698, 2007 WL 203943, at \*10 (D.N.J. Jan. 24, 2007) (citing 3 James W. Moore et al., *Moore's Federal Practice* § 16.14[1][b] (3d ed.1997)).

**(ii) Rule 15**

Rule 15 provides that once a responsive pleading has been filed, “a party may amend its pleadings only with the opposing party’s written consent or the court’s leave.” Fed. R. Civ. P. 15(a)(2). Leave to amend is to be freely granted unless there is undue delay or prejudice, bad faith or dilatory motive, failure to cure deficiencies through previous amendment, or futility. *Foman v. Davis*, 371 U.S. 178, 182 (1962). The ultimate decision to grant or deny leave to amend is a matter committed to the court’s sound discretion. *See, e.g., Zenith Radio Corp. v. Hazeltine Research, Inc.*, 401 U.S. 321, 330 (1970). The Third Circuit has “made clear that there is to be a liberal use of Rule 15 to amend complaints so as to state additional causes of action.” *Leased Optical Dep’t, Inc. v. Opti-Center, Inc.*, 120 F.R.D. 476, 479 (D.N.J. 1988) (quotes omitted); *see also Mullin v. Balicki*, 875 F.3d 140 (3d Cir. 2017) (“liberal amendment regime” aids policy “favoring resolution of cases on their merits”).

**B. Summary of the Motion**

Plaintiffs concede that the Complaints do not “explicitly recite[] that any of Defendants’ infringement was willful and that plaintiffs sought enhanced damages.” (Pls.’ Br. 3.) The Complaints also made no mention of infringement by the doctrine of equivalents. Accordingly, as early as May 2016 (discussed below), Plaintiffs acknowledged that they would have to amend the pleadings to include claims of willful infringement and the doctrine of equivalents.

In June 2017, during discovery and despite no effort to amend the complaints to that point, Plaintiffs attempted to serve discovery requests that sought information relating to willful infringement, including “any pre-suit investigation into the Asserted Patents and asking whether each Defendant intend to rely on the advice of counsel.” Defendants refused to answer the discovery on the grounds that willfulness was not pleaded in the Complaints.

Defendants claim that the motion to amend is “a microcosm of a much larger problem in Plaintiffs’ conduct throughout these cases,” and that “a pattern of delay and second guessing past-strategic decisions” has been present throughout Plaintiffs’ prosecution of the case. (Defs.’ Br. 1.)<sup>2</sup> Defendants claim that Plaintiffs have been dilatory and failed to meet numerous scheduling order deadlines, and that allowing amendments into the case now would be prejudicial and will result in additional

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<sup>2</sup> The Court declines to recite past discovery disputes or attribute blame to any party. However, it is noted that discovery was not smooth for large periods of time in the case.

discovery and expense. Defendants also contend any claims alleging willfulness would be futile.

Plaintiffs claim that Defendants were generally aware that they intended to bring willfulness into the case. At the same time, Plaintiffs do not explain the request to include an amended claim of infringement based on the doctrine of equivalents, other than to say they don't know whether it could be necessary as a result of claim construction.<sup>3</sup> Regardless, they claim that there is no prejudice to allowing the claims now because dispositive motions have not been filed, some discovery remains, and a trial is not imminent.

### C. **Decision**

Plaintiffs' request to amend to drop the infringement claims relating to all patents other than the '128 patent and to add certain nominal defendants is unopposed, and therefore, is **granted**. However, Plaintiffs' request to include additional claims for willful infringement and any claim alleging infringement by the doctrine of equivalents is **denied**.

The deadline for amending pleadings was September 8, 2016. To establish good cause, the movant must show that "despite its diligence, it could not reasonably have met the scheduling order deadline." *Hutchins*, 2005 WL 1793695, at \*3.

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<sup>3</sup> Indeed, at oral argument, Plaintiffs' counsel stated "[w]ith respect to equivalents, as we said, we're not really arguing that anything is infringing under the doctrine of equivalents at this point. We think there's literal infringement. We just don't want to be precluded because the words "the doctrine of equivalents" are not in the complaint . . . ." (Transcript of Oral Argument, October 25, 2018, at 17.)

Plaintiffs have not met that burden. Plaintiffs could have included willful infringement and the doctrine of equivalents at the time the cases were filed and certainly prior to the amendment motion deadline. Nothing has changed that would justify further amendment to the pleadings at this time. The following timeline is illustrative:

- \* ***November 2015*** – Plaintiffs file the Complaints that do not explicitly include willful infringement and infringement by the doctrine of equivalents.
- \* ***May 9, 2016*** - Plaintiffs serve infringement contentions in which they acknowledge willful infringement is not in the case by stating that they “intend to seek leave to amend the Complaint to allege willful infringement and to request appropriate remedies upon proof of same.” (See Declaration of James S. Richter, Esq., (“Richter Decl.”) Exs. 1-3.)<sup>4</sup>
- \* ***October 2016*** - Defendants served non-infringement contentions noting that Plaintiffs failed to plead both willful infringement and infringement under the doctrine of equivalents in the Complaint. (Richter Decl., Exs. 4-6.)
- \* ***June 2017*** – Plaintiffs serve discovery on the question of willful infringement. (Richter Decl., Exs. 7-9.)
- \* ***July 5, 2017*** - Defendants again advise Plaintiffs that they have not pleaded willful infringement and that discovery on the subject is inappropriate because it is not part of the case. (Richter Decl., Exs. 10-12.)
- \* ***Discovery is scheduled to close – November 2017***
- \* ***November 21, 2017*** – Plaintiffs email Defendants’ counsel asking to discuss an intention to seek leave to file an amended complaint to include willfulness. (Richter Decl., Ex. 13.)

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<sup>4</sup> This admission undercuts any suggestion in Plaintiffs’ brief that willfulness was “implicitly” pleaded in the original Complaints.

- \* ***December 4, 2017*** - Defendants advise Plaintiffs' counsel that they do not consent to any amendment to include willfulness, which could have been included in the initial complaint. (Richter Decl., Ex. 14.)
- \* ***February 7, 2018*** - Plaintiffs first write to the Court seeking leave to amend. (ECF No. 196.)

Plaintiffs have not shown “good cause” to amend. Willful infringement and the doctrine of equivalents may be included in an initial pleading. They weren’t. Plaintiffs acknowledged in their initial disclosures in May 2016, prior to the deadline to amend, that they would have to seek to amend their complaints to include these subjects. (Richter Decl., Exs. 1-3.) They didn’t. Defendants advised Plaintiffs in their non-infringement contentions served in October 2016 that willfulness was not pleaded and they did not consider it part of the case. (Richter Decl., Exs. 4-6.) Plaintiffs did nothing. In December 2017, Defendants rejected Plaintiffs’ request to consent to an amendment to include willfulness. (Richter Decl., Ex. 1.) Despite being more than a year after the amendment deadline, Plaintiffs did nothing until February 2018.

Plaintiffs have no reasonable explanation for the delay, except to vaguely reference some unidentified discovery from *one* (of three) Defendants – Glenmark – served in October 2017, which they claim contained “additional evidence” of Glenmark’s willful infringement. It is not a legitimate excuse. Moreover, even if some discovery provided some “additional” basis to plead willfulness as to Glenmark, it has nothing to do with Defendants Amneal and Roxane. Also, Plaintiffs own

representation that the discovery provided “additional evidence” as to Glenmark necessarily means that Plaintiffs were in possession of at least *some* evidence prior to receiving discovery responses in October 2017.

Since Plaintiff has not shown good cause for the late amendment relating to willfulness and the doctrine of equivalents, the motion is denied pursuant to Rule 16, and there is no need to analyze the Rule 15 factors. *See Eastern Minerals & Chem. Co.*, 225 F.3d at 340.

Notwithstanding, even if Plaintiffs could show good cause, the amendment would still be disallowed under Rule 15 due to the prejudice to Defendants and the burden on the Court. Prejudice is paramount. *See Lorenz v. CSX Corp.*, 1 F.3d 1406, 1414 (3d Cir. 1993) (“Prejudice to the non-moving party is the touchstone for the denial of an amendment.”). Prejudice is generally evaluated by looking at whether the amendment would: (1) require the non-moving party to expend significant additional resources to conduct discovery and prepare for trial; (2) significantly delay the resolution of the dispute; or (3) prevent the non-moving party from bringing a timely action in another forum. *See, e.g., Long v. Wilson*, 393 F.3d 390, 400 (3d Cir. 2004).

Amendment at this time would be problematic and prejudicial. The case is already more than three-years-old. Prior to the late request to amend, discovery was supposed to be over and the case ready for expert discovery and dispositive motion practice. To permit Plaintiffs to add new claims now would undoubtedly seriously delay the proceedings, require substantial amounts of additional discovery, and

increase costs to the opposing party. Moreover, to the extent Plaintiffs would include a claim for infringement by the doctrine of equivalents, it could impact claim construction submissions and the *Markman* hearing, which was already held. No explanation has been offered why that should be allowed when the doctrine of equivalents could have been asserted at the outset of the case.

Finally, Defendants raise a threshold question of futility that would be the subject of a Rule 12(b)(6) motion before District Judge Cecchi. (*See* Transcript of Oral Argument, October 25, 2018, at 24 (DEFENSE COUNSEL: “Finally, on futility, . . . this is hotly disputed . . . [S]o I don’t know if you have to decide that today. We don’t think there’s good cause. But I can tell you, I expect we’ll be back with a motion to dismiss if there is an amendment.”)). Such pre-answer motion practice more than 3 years into the case would further unnecessarily delay the case, increase costs, and deplete and distract party and court resources, all of which could have been avoided had Plaintiffs moved diligently to amend their Complaints.

### **III. Request to Amend Infringement Contentions**

Plaintiffs seek to amend their infringement contentions against Defendant Glenmark to include “further information establishing its willful infringement.” Plaintiffs concede, however, that if the motion to amend the Complaint is denied, this motion would be moot. (*See* Transcript of Oral Argument, October 25, 2018, at 18.) Accordingly, the request to amend infringement contentions is **DENIED**.

#### **IV. Request to Amend Responses to Invalidity Contentions**

Plaintiffs seek to amend their Responses to Defendants' Invalidity Contentions to cite a new decision of the European Technical Board of Appeal regarding the European counterpart to the '128 patent. Since the decision is new and post-dates Plaintiff's original invalidity responses, Defendants have no objection. As such, the motion is **GRANTED**.

#### **CONCLUSION**

For the reasons stated above, Plaintiffs' motion for leave to file amended complaints is **GRANTED IN PART AND DENIED IN PART**; Plaintiffs' motion for leave to file amended infringement contentions is **DENIED**; and Plaintiffs' motion for leave to file amended invalidity contentions is **GRANTED**. An appropriate Order will be entered.

**s/Mark Falk**  
**MARK FALK**  
**United States Magistrate Judge**

**Dated: November 2, 2018**